UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ZELTIQ AESTHETICS, INC.,

Plaintiff,

v.

BTL INDUSTRIES, INC., et al.,

Defendants.

Case No. 13-cv-05473-JCS

ORDER DENYING PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Re: Dkt. No. 65

I. INTRODUCTION

This case concerns two medical devices used for the reduction of body fat and related aesthetic procedures. One of them, produced by Plaintiff Zeltiq Aesthetics, Inc. ("Zeltiq"), received clearance from the Food and Drug Administration ("FDA") for such use. The other, produced by Defendant BTL Industries, Inc. ("BTL"), was cleared only for unrelated therapeutic uses. Zeltiq brought this action against BTL and Defendant Saturn Consulting LLC, claiming that Defendants' marketing of BTL's device violates federal, California, and Massachusetts laws regarding false advertising and unfair competition. Zeltiq now moves for partial summary judgment on its claim that Defendants' "off-label" marketing is unlawful conduct under California's Unfair Competition Law ("UCL"). For the reasons stated below, Zeltiq's Motion is DENIED.[1]

II. BACKGROUND

A. FDA Premarket Approval and 510(k) Clearance

In 1976, Congress amended the federal Food, Drug, and Cosmetic Act ("FDCA"), which previously only regulated food and drugs, with the Medical Device Amendments ("MDA"), 90

[1] The parties have consented to the jurisdiction of the undersigned magistrate judge for all purposes pursuant to 28 U.S.C. § 636(c).

Stat. 539, 21 U.S.C. § 301. The MDA "classif[y] medical devices in three categories based on the risk that they pose to the public." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). As explained by the Supreme Court in *Medtronic*:

> Devices that present no unreasonable risk of illness or injury are designated Class I and are subject only to minimal regulation by "general controls." 21 U.S.C. § 360c(a)(1)(A). Devices that are potentially more harmful are designated Class II; although they may be marketed without advance approval, manufacturers of such devices must comply with federal performance regulations known as "special controls." § 360c(a)(1)(B). Finally, devices that either "presen[t] a potential unreasonable risk of illness or injury," or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are designated Class III. § 360c(a)(1)(C).

Id. at 476−77. While "Class III devices must complete a thorough review process with the FDA before they may be marketed," *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001), Class I and II devices only need to submit a "'premarket notification' to the FDA, in accordance with the less burdensome '510(k) process.'" *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 925 (9th Cir. 2010) (quoting *Medtronic*, 518 U.S. at 477−79).

"Under the 510(k) process,[2] if the Class II device is deemed 'substantially equivalent' to a pre-existing device with prior clearance, 'it can be marketed without further regulatory analysis.'"[3] *Id*. (citing *Medtronic*, 518 U.S. at 478; 21 U.S.C. § 360(k); 21 C.F.R. § 807.100). "'[S]ubstantial equivalence' means, with respect to a device being compared to a predicate device, that the device has the *same intended use* as the predicate device . . . ." 21 U.S.C. § 360c(i)(1)(A) (emphasis added); *see also* 21 C.F.R. § 807.100 ("FDA will determine that a device is substantially equivalent to a predicate device [if, *inter alia*, it has] the *same intended use* as the predicate device." (emphasis added)).

[2] The process, codified at 21 U.S.C. § 360(k), is more commonly known as "section 510(k)" because that was "the section in the original Act." *Medtronic*, 518 U.S. at 478.

[3] "Unlike premarket approval, 510(k) clearance 'does not in any way denote official approval of the device.'" *PhotoMedex*, 601 F.3d at 925 n. 3 (quoting 21 C.F.R. § 807.97).

B. Factual Background

1. Zeltiq's CoolSculpting System

Zeltiq manufactures and markets a medical device known as CoolSculpting. Altavilla Decl. (dkt. 18-3) ¶ 6. CoolSculpting is designed to reduce the temperature of fat cells in the treated area, causing fat cell elimination through a natural biological process known as "apoptosis" without causing scar tissue or damage to the skin, nerves, or surrounding tissue. *Id.* ¶ 7. CoolSculpting is clinically shown to reduce fat bulges in a sixty-minute procedure. *Id.*

Zeltiq's CoolSculpting system has been cleared by the FDA for cold-assisted lipolysis of the flank, or "love handles," and the abdomen. *Id.* ¶ 6. Zeltiq states that it "developed its CoolSculpting technology for a novel indication," and therefore, "submitted clinical studies and other data to FDA to obtain 510(k) clearance for CoolSculpting." *Id.* ¶ 8. Zeltiq states that it undertook the expensive endeavor of obtaining 510(k) clearance because clearance of a device for treatment of body fat conveys instant and substantial credibility to the device. *Id.*

CoolSculpting has become the leading noninvasive medical device for reduction of body fat. *Id.* ¶ 9. In a quarterly financial filing, Zeltiq reports having sold over 1,900 CoolSculpting devices, including over 500 in the twelve months between September 30, 2012 and September 30, 2013. Faucette Prelim. Inj. Decl. (dkt. 20-1) ¶ 2 & Ex. A at 19. Zeltiq also reports having generated over $75 million in revenue in the nine months ending in September 30, 2013. *Id.* In a preliminary full year report, Zeltiq noted that its revenue increased approximately 91% in one year. *Id.* Ex. G.

2. BTL's Vanquish Device

a. FDA Clearance

BTL submitted a notice of intent to the FDA under § 510(k) to market a device that, at that time, it called "BTL Elite." *See* Hanrahan Decl. (dkt. 56-2) ¶ 3 & Ex. 3 (dkt. 56-3). Like certain predicate devices identified in BTL's 510(k) report, the BTL Elite was "intended for the therapeutic application of deep heating." *Id.* Ex. 3 at ECF p. 5. BTL asked for FDA clearance to market its device for the same purpose as the predicate devices, specifically "treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the

treatment of malignancies," and represented that "[t]he BTL Elite System is substantially equivalent to its predicate devices when used according to its intended use." *Id.* at ECF pp. 5, 6. The FDA reviewed the 510(k) report, "determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicated devices," and signed off on an "Indications for Use Statement" that reads as follows:

> Indications for use: Indications for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as: 1. Relieving pain; 2. Reducing muscle spasm; 3. Increasing range of motion of contracted joints using heat and stretch techniques; and 4. Increasing blood flow to tissues in the treatment area.

Id. at ECF pp. 7–9.

Neither BTL's notice to the FDA, nor the FDA's letter approving clearance, discussed the use of the device for aesthetic procedures such as fat reduction. *See id.* Subsequently, however, at least one peer-reviewed article published in a medical journal concluded that the device, now marketed as Vanquish, "is safe and effective for body contouring, fat, and circumferential reduction." Kateřina Fajkošová, et al., *Selective Radiofrequency Therapy as a Non-Invasive Approach for Contactless Body Contouring and Circumferential Reduction*, 13 J. Drugs in Dermatology 291 (2014) (available in the record as Faucette Decl. Ex. B, dkt. 58-3).

b. Marketing and Promotion of Vanquish

Although BTL understood that its 510(k) clearance did not include "an indication for use in body contouring or fat reduction," it "anticipated that doctors would buy Vanquish and then promote [Vanquish] to their patients as a device to reduce patients' body fat." Hanrahan Decl. Ex. 1 (Besse Dep., dkt. 65-1) 39:25–40:20, 66:11–15.[4] Kevin Meyers, who operates Defendant Saturn Consulting LLC and sold Vanquish devices to doctors, testified that although fat reduction is an "off-label use," that was the only purpose for which Vanquish was sold. Hanrahan Decl. Ex. 6 (Meyers Dep., dkt. 65-3) 68:1–69:11; *see* Answer (dkt. 17) ¶ 10. To the knowledge of BTL's president Marcel Besse, no physicians bought the device for any other use. Besse Dep.

[4] Defendants object to the admissibility of much of the evidence Zeltiq has submitted in support of its Motion. The Court assumes for the sake of argument that all of Zeltiq's evidence is admissible.

71:24−72:6.

Until recently, BTL's website continued to promote Vanquish "for all healthy patients who want to take control of their core and improve problem areas when exercise and diet have failed," and "who desire aesthetic improvement without the cost and recovery time of surgery." *For Patients*, BTL Aesthetics, www.btlaesthetics.us/for-patients (copyright 2015, accessed March 9, 2015). In a section addressing the kinds of results that patients can expect, the website stated that although "[r]esults may vary from patient to patient . . . [m]easurable waist reduction is common." *Id.* Although those references to Vanquish appear to have been recently removed from BTL's website, a section of the website labeled "FDA Clearances" continues to state that "Vanquish . . . can be used for the non-invasive temporary reduction of waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use." *FDA Clearances*, BTL Aesthetics, accessed by selecting the "FDA CLEARANCES" button at the bottom of www.btlaesthetics.us/for-patients (copyright 2015, accessed March 23, 2015).

There is a great deal of evidence in the record regarding Defendants' promotion of Vanquish. The parties dispute the conclusion that should be drawn from the evidence. For the purpose of the present Motion, however, the Court assumes for the sake of argument that Defendants have marketed Vanquish for aesthetic procedures such as fat reduction and continue to do so—as discussed below, even granting Zeltiq that assumption, the Motion must be denied.

c. Vanquish Operator's Manual

The Vanquish device is packaged with a forty-five page Operator's Manual addressing such issues as "safety precautions," "assembly and set-up," and "operating instructions." *See generally* Hanrahan Decl. Ex. 3 (dkts. 56-4, 56-5). For the most part, these instructions appear to apply to any use of Vanquish to apply deep heat to tissue, without regard to the purpose for which a doctor might seek to apply such heat. *See id.* at, e.g., 31−37 (section covering "Operating Instructions," which does not discuss any difference in operation for different medical indications). Two paragraphs addressing "Intended Use and Indications for Use" restate the indications listed in BTL's 510(k) report and the FDA-cleared statement of indications. *Id.* at 5.

Like those documents, the Operator's Manual does not discuss the use of Vanquish for aesthetic procedures. *See id.*

C. Procedural History

Zeltiq filed this action in November of 2013, alleging that although Vanquish had not received FDA clearance for fat reduction, "Defendants launched a marketing campaign to leverage the FDA clearance it did have by promoting Vanquish solely as a fat reduction device while stating that it had FDA clearance and implying, falsely, that this clearance was for the promoted use." Compl. (dkt. 1) ¶ 19. Zeltiq claims that such promotion violates: (1) the federal Lanham Act, 15 U.S.C. § 1125; (2) California's UCL, Cal. Bus. & Prof. Code § 17200, as both unlawful and deceptive conduct; and (3) the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A. Compl. ¶¶ 38−63. Zeltiq's Complaint seeks injunctive relief barring "Defendants from promoting the Vanquish device in any manner that suggests or implies that it enjoys clearance by FDA for fat reduction" and "requiring Defendants to disclose prominently in all promotion for the Vanquish device that FDA has not cleared it for fat reduction, but FDA has approved other devices for that use." *Id.* at 15 (prayer for relief). Zeltiq also seeks attorneys' fees. *Id.* Defendants filed an Answer admitting that "Vanquish is not FDA cleared for body sculpting or fat reduction," but denying deceptive or unlawful conduct and denying liability. *See* Answer ¶ 41.

On March 25, 2014, the Court denied Zeltiq's motion for a preliminary injunction. *See generally* Order Denying Mot. for Prelim. Inj. ("PI Order," dkt. 32).[5] The Court considered Zeltiq's claims for false or misleading advertising under all three statutes together, and held that Zeltiq had not shown a likelihood of success, but had raised serious questions going to the merits. *Id.* at 12−17. With respect to Zeltiq's "unlawful conduct" claim under the California UCL, the Court first rejected Zeltiq's argument that Defendants' marketing practices violated section 111550 of the California Health & Safety Code. *Id.* at 17−18. The relevant portion of that statute requires only that a device be "reported under Section 510(k) of the federal act," with no reference to a device's actual or intended use, and BTL had received section 510(k) clearance for Vanquish.

[5] *Zeltiq Aesthetics, Inc. v. BTL Indus., Inc.*, 32 F. Supp. 3d 1088 (N.D. Cal. 2014).

Id. The Court then turned to Zeltiq's argument that Vanquish was "misbranded" under various other sections of the Health & Safety Code, and held that Zeltiq raised serious questions but failed to show a likelihood of success. *Id.* at 18−19.

The Court determined that Zeltiq also failed to show that the balance of hardships tipped sharply in its favor, or that it would suffer an irreparable injury in the absence of a preliminary injunction. *Id.* at 19−20. The Court therefore denied Zeltiq's motion. *See id.* at 21.

D. Zeltiq's Present Motion for Partial Summary Judgment

Zeltiq now moves for summary judgment on its UCL claim, arguing that it is entitled to judgment based on evidence that BTL's marketing of Vanquish violated and continue to violate state law, and is therefore actionable under the UCL as an "unlawful" business practice. *See* Mot. (dkt. 65) at 1. The present Motion does not encompass Zeltiq's separate theory that Defendants' marketing constitutes false or deceptive advertising under the UCL, the Lanham Act, or the Massachusetts Consumer Protection Act. *See generally id.* Zeltiq now seeks somewhat different relief than requested in the Complaint: an injunction against "selling Vanquish for anything other than the FDA-cleared uses, and order[ing BTL] to recall units it has sold in California to date." *Id.* at 20. Defendants have not moved for summary judgment.

Zeltiq first argues that the sale of Vanquish for aesthetic procedures violates Health & Safety Code section 111550. *Id.* at 13−17. Although the applicable provision of that statute requires only that a *device* be reported under section 510(k)—and the Court specifically rejected Zeltiq's arguments otherwise in denying Zeltiq's preliminary injunction motion—Zeltiq again contends that other provisions of section 111550 and the underlying structure of the section 510(k) process support reading the statute to bar sales of devices for any *purposes* not reported under section 510(k). *See id.* Defendants respond that the Court should reaffirm its previous holding that marketing Vanquish for any purpose does not violate section 111550, because Vanquish meets the criteria of a "device that is reported under section 510(k)." Opp'n (dkt. 58) at 8−9; Cal. Health & Safety Code § 111550(a)(3). Defendants also argue that there is a genuine issue of fact as to the nature of their marketing activities. Opp'n at 12−13.

Zeltiq next argues that Defendants' marketing of Vanquish violates Health & Safety Code

section 111440 because Vanquish is "misbranded" under the definition provided in Health & Safety Code section 111375(a), which requires that a device's labeling bear "[a]dequate directions for use." Mot. at 17. In order to reach its conclusion that the Vanquish directions are inadequate beyond any genuine dispute of fact, Zeltiq relies on the federal regulatory scheme underlying the FDCA, on the basis that "[w]here the wording and objectives of a California statute are similar to the wording and objectives of a federal statute, California courts look to interpretations of the federal statute for guidance in interpreting the state statute." *Id.* at 17 (quoting *United States v. Johnson Controls, Inc.*, 457 F.3d 1009, 1021 (9th Cir. 2006)). The federal regulations require that prescription devices include:

> adequate information for . . . use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented.

21 C.F.R. § 801.109(d); *see* Mot. at 18. According to Zeltiq, the Vanquish packaging (including the Operator's Manual) does not meet this standard because it does not discuss the use of Vanquish for fat reduction, the "purpose[] for which [Vanquish] is advertised or represented." *Id.* at 18−19.

Defendants respond that the instructions in the Operator's Manual are adequate for any use of Vanquish, including for fat reduction or other aesthetic procedures. Opp'n at 9−12. Defendants observe that no evidence in the record indicates either that fat reduction would require different instructions, or that any patients have been harmed due to inadequate labeling. *Id.* at 10−11. In its Reply, Zeltiq contends that, if nothing else, Defendants have violated the regulatory requirement that packaging include "indications" for "all purposes for which [the device] is advertised or represented." Reply (dkt. 66) at 9 (quoting 21 C.F.R. § 801.109(d)) .

Defendants also argue that official FDA guidance permitting device manufacturers to provide doctors with peer-reviewed articles suggests that selling a device for an off-label use does not constitute misbranding. Opp'n at 11−12. Zeltiq responds that it is not challenging the provision of such articles, and that even if the FDA permits manufacturers to sell devices when

they *know* that doctors intend off-label usage, that would not shield Defendants' purported failure to "include adequate directions for using the device as BTL actually *intends*, *advertises* and *represents*." Reply at 9 (emphasis added).

In addition to responding to Zeltiq's arguments, Defendants raise several arguments of their own. First, Defendants contend that that Zeltiq has failed to establish standing under the UCL. Opp'n at 3−5. Zeltiq, which did not address standing in its Motion, submitted new evidence with its Reply that purports to show financial harm caused by competition from Vanquish. *See* Reply at 1−3; *see generally* Hanrahan Supp'l Decl. & Exs. (dkts. 60, 66). The Court denied Defendants' request to disregard that evidence, and instead granted Defendants leave to file a surreply. *See* dkt. 64. Defendants' Surreply challenges the sufficiency of the evidence that Zeltiq suffered harm. *See generally* Surreply (dkt. 67).

Defendants also argue that Zeltiq's claims are preempted by the FDCA and MDA, Opp'n at 5−7, and that even if Defendants' conduct is found to be unlawful, Zeltiq has not established that it is entitled to injunctive relief, *id.* at 14 (citing *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006)). Zeltiq responds that its claims are not preempted because the state laws on which it relies parallel, rather than conflict with, the FDCA, and that it need not meet the *eBay* test for injunctive relief because the UCL sets forth a more lenient standard. Reply at 9−13.

III. ANALYSIS

A. Legal Standard for Summary Judgment

Summary judgment on a claim or defense is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Once the movant has made this showing, the burden then shifts to the party opposing summary judgment to designate "specific facts showing there is a genuine issue for trial." *Id.* "[T]he inquiry involved in a ruling on a motion for summary judgment . . . implicates the substantive evidentiary standard of proof that would apply at the trial on the merits." *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 252 (1986). On summary judgment, the court draws all reasonable factual inferences in favor of the non-movant, *Scott v. Harris*, 550 U.S. 372, 378 (2007), but where a rational trier of fact could not find for the non-moving party based on the

record as a whole, there is no "genuine issue for trial" and summary judgment is appropriate. *Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986).

B. California's Unfair Competition Law

California's UCL prohibits unfair competition, defined as "any unlawful, unfair, or fraudulent business act or practice." Cal. Bus. & Prof. Code § 17200. In its present Motion, Zeltiq pursues only the "unlawful" prong of the UCL. *See* Mot. at 1 (arguing that "all of BTL's sales and efforts to sell Vanquish within California were and remain unlawful under state law, and therefore in violation of . . . § 17200."). A "person who has suffered injury in fact and has lost money or property as a result of the unfair competition" may bring an action to enjoin such practices. *Id.* §§ 17203, 17204. "If a party has . . . proven a personal, individualized loss of money or property in any nontrivial amount, he or she has also . . . proven injury in fact." *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 325 (2011); *see also id.* at 324 & n.7 (noting with approval the federal Article III standing requirement of an "'identifiable trifle' of injury" (citations omitted)).

Defendants dispute whether Zeltiq has adequately shown injury in fact, as well as whether Zeltiq's claim meets the criteria for injunctive relief. *See* Opp'n at 3−5, 14; *see generally* Surreply. The Court assumes for the sake of argument that Zeltiq has shown injury, and does not reach the issue of whether Zeltiq would be entitled to an injunction. For the reasons discussed below, the Court finds that Zeltiq has not shown actionable unlawful conduct.

C. The FDCA Grants the United States Exclusive Enforcement Authority

The FDCA and related federal regulations prohibit, in at least some circumstances, the promotion of covered medical devices for uses not cleared or approved by the FDA. *See Hawkins v. Medtronic, Inc.*, No. 1:13-CV-00499 AWI, 2014 WL 6611876, at *4−5 (E.D. Cal. Nov. 20, 2014) (discussing inconsistent authority within the Ninth Circuit regarding whether and when off-label promotion violates the FDCA). However, with the exception of certain claims brought by individual states, "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court has held that "[t]he FDCA leaves no doubt that it is the Federal Government rather than private

litigants who are authorized to file suit for noncompliance with the medical device provisions," and that § 337(a) also bars private state-law claims that "exist solely by virtue of the FDCA . . . requirements." *Buckman Co. v. Plaintiffs' Legal Comm.*, 431 U.S. 341, 349 n.4, 353 (2001). Likely on that basis, Zeltiq's present Motion does not argue that Defendants' violation of the FDCA itself supports an unlawful conduct claim under the UCL. *See generally* Mot. Instead, Zeltiq contends that Defendants' marketing of Vanquish is "unlawful" under two provisions of California's Health & Safety Code: section 111550, which prohibits the sale of unapproved medical devices, and section 111440, which prohibits the sale of misbranded medical devices.

D. Defendants' Conduct Does Not Violate Health & Safety Code Section 111550

Zeltiq argues that Defendants violate section 111550 of the California Health & Safety Code by selling Vanquish for uses not cleared by the FDA. Mot. at 13−17. According to Zeltiq, such sales are therefore actionable under the UCL as an unlawful business practice. *Id.* at 13. The Court considered and rejected this argument in the context of Zeltiq's preliminary injunction motion, and finds no basis now to alter that conclusion.

Health & Safety Code section 111550 provides, in relevant part, as follows:

> No person shall sell, deliver, or give away any new drug or new device unless it satisfies *either of* the following:
>
> (a) It is one of the following:
>
> . . .
>
> (3) A device that is reported under Section 510(k) of the federal act (21 U.S.C. Sec. 360(k)), or is a device exempted pursuant to subsection (l) or (m) of Section 360 of Title 21 of the United States Code, or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under Section 515 of the federal act (21 U.S.C. Sec. 360e).
>
> [or]
>
> (b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended. Any person who files a new drug or device application with the department shall submit, as part of the application, all of the following information:
>
> (1) Full reports of investigations that have been made to

> show whether or not the new drug or device is safe for use and whether the new drug or device is effective in use under the conditions prescribed, recommended, or suggested in the labeling or advertising of the new drug or device.
>
> . . .

Cal. Health & Safety Code § 111550 (emphasis added). As Zeltiq partially acknowledges, "[s]ubsection (b) has no bearing here—BTL did not seek or receive approval from the State [of California] to sell Vanquish." Mot. at 14. Further, even if BTL had sought or received such approval, subsection (b) would still have no bearing because a device need only meet "either of" the two conditions—subsection (a) or (b)—and Vanquish meets subsection (a) as a "device that is reported under Section 510(k)." *See* § 111550.

Zeltiq nevertheless asks the Court to read into subsection (a)(3) the requirement that the device not merely be reported, but also that it is sold for the same *purpose* for which it was reported. Mot. at 14−17. Zeltiq bases this argument on both the structure of section 111550 and the nature of the FDA's section 510(k) clearance process.

First, Zeltiq argues that subsection (b) of section 111550 is relevant because it "illuminates State policy that safety and effectiveness *for the intended use* be verified either by the State through its own process, or by the FDA through the 510(k) clearance or the premarket approval process." *Id.* at 14. Zeltiq's argument is essentially that when a statutory scheme creates two alternatives, conditions that are only explicitly attached to one alternative should be read into both. As the Supreme Court very recently observed, "[t]his inverts normal rules of interpretation." *Ala. Dep't of Revenue v. CSX Transp., Inc.*, 575 U.S. __, No. 13-553, 2015 WL 893045, at *5 (Mar. 4, 2015) (slip op. at 6−7) (holding that where the first three subsections of a statute specified a comparison class and the fourth did not, "the explicit limitation . . . in the first three provisions, and the absence of such a limitation in the fourth, suggests that no such limitation applies to the fourth"). Under the "normal rules of interpretation," *see id.*, the California statute's explicit reference to the "conditions prescribed, recommended, or suggested" for use of a device in subsection (b) can be read to *emphasize* rather than negate the omission of such considerations in subsection (a). *See* § 111550. The Court therefore declines to adopt Zeltiq's proposed reading of the statute.

Next, Zeltiq argues that subsection (a) is implicitly use-specific because the section 510(k) reporting process that it references takes into account the intended uses of the device. Mot. at 14−17 (citing, *e.g.*, 21 C.F.R. §§ 807.100(b)(1), 807.87(h), 807.92(a)(5)). Despite Zeltiq's extensive review of FDA regulations concerning a device's intended use, there is nothing in the California statute to indicate that it encompasses such considerations.

Any number of legitimate policy concerns could have led the California legislature to intentionally limit subsection (a) to the question of whether a *device*, rather than a specific *use* for the device, has been reported under the federal 510(k) process. The legislature may well have desired to create an alternative state-specific track, under subsection (b), for devices not cleared by the FDA, without altering or supplementing the existing federal regulation of other devices that have received clearance under section 510(k). Perhaps the legislature did not wish to burden the state courts with examining the scope of use covered by a 510(k) report, as opposed to merely whether such a report existed. Or perhaps the legislature did not wish to intrude on the federal government's exclusive authority to enforce the MDA. *See* 21 U.S.C. § 337(a); *Buckman*, 531 U.S. at 349 n.4, 352. The fact is that subsection (a) says nothing of a device's intended use, and Zeltiq has cited no authority indicating that the legislature intended that subsection to require anything more than FDA clearance of a *device*—regardless of how that device is used.

Zeltiq's reference to the District of Arizona's decision in *Ramirez v. Medtronic Inc.* is unavailing because that case, based on Arizona law, says nothing about California law in general or section 111550 specifically. *See* Mot. at 15 (citing *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 997, 990 (D. Ariz. 2013)). The court in *Ramirez* held that "[w]hen [a] device is not being used in the manner the FDA pre-approved and the manufacturer is actually promoting such use, there is no law or policy basis on which to pre-empt the application of state law *designed to provide that protection*." *Ramirez*, 961 F. Supp. 2d at 991. In this case, however, there is no indication that section 111550 is "designed to provide that protection," because that statute addresses only whether a device has been reported under section 510(k), not the specific use for which it was reported. *Ramirez* therefore has no bearing on this case, and the Court need not address whether its controversial non-preemption holding was correctly decided. *See, e.g.*, *Beavers-Gabriel v.*

Medtronic, Inc., 15 F. Supp. 3d 1021, 1035 (D. Haw. 2014) ("*Ramirez* has been rejected—for good reason—by numerous courts."); *Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026, 1036 (D. Ariz. 2014) (same, quoting *Beavers-Gabriel*).

The Court reaffirms its previous holding that subsection (a)(3) of section 111550 requires only what it says, and that selling a "device that is reported under Section 510(k)" does not violate that law, regardless of the device's intended use. *See* § 111550(a)(3); PI Order at 17−18. There is no dispute in this case that the device now branded as Vanquish was "reported under Section 510(k)." Accordingly, Defendants' sale of Vanquish does not violate section 111550, and that statute provides no basis for Zeltiq's UCL claim for unlawful business practices.

E. Zeltiq Has Not Shown That Defendants' Branding of Vanquish Violates Health & Safety Code Section 111440

Section 111440 of the California Health & Safety Code provides that "[i]t is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded." Cal. Health & Safety Code § 111440; *see also id.* §§ 111445, 111450 (imposing additional prohibitions against misbranding). Section 111375 of the Health & Safety Code provides further guidance, stating that a "device is misbranded unless its labeling bears . . . [a]dequate directions for use." Cal. Health & Safety Code § 111375.

The Vanquish device is packaged with a forty-five page Operator's Manual addressing such issues as "safety precautions," "assembly and set-up," and "operating instructions." *See generally* Hanrahan Decl. Ex. 3. Neither party argues that the Operator's Manual falls outside the scope of "labeling" contemplated by section 111375. Zeltiq, however, argues that the instructions are not "adequate" because they do not address BTL's intended use of the device—i.e., fat reduction and "body contouring." *See* Mot. at 17−19. In response, Defendants correctly observe that "[t]here is no evidence in the record that using the device to reduce fat requires physicians to somehow deviate from the standard instructions in the manual." Opp'n at 10. Even if *some* such evidence existed, it is unlikely that the Court, drawing all reasonable inferences in Defendants' favor for the purpose of Zeltiq's present motion, would be able to conclude that there is not at least a genuine factual issue for trial as to the whether the generic instructions in the Operator's Manual

are adequate for fat reduction.

In order to reach the conclusion that the Operator's Manual is unambiguously inadequate, Zeltiq looks to federal regulations promulgated under the FDCA and MDA. Mot. at 17−18. A California appellate court, considering a claim implicating the federal statutes, has summarized the application of those regulations to prescription medical devices:

> "Adequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended." (21 C.F.R. § 801.5 (2009).) By definition, "adequate directions for use" cannot be prepared for prescription devices such as the [device at issue], because these devices must be used under the supervision of a licensed practitioner. However, such devices will escape the deemed designation of being "misbranded" where, among other conditions, "[l]abeling on or within the package from which the device is to be dispensed bears information for use, including *indications*, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and *for the purpose for which it is intended, including all purposes for which it is advertised or represented* . . . ." (*Id.*, § 801.109(c).)

Weinstat v. Dentsply Int'l, Inc., 180 Cal. App. 4th 1213, 1219 (2010) (emphasis added);[6] *see also* 21 C.F.R. § 801.109.

Zeltiq argues that the Vanquish Operator's Manual does not meet this standard because fat reduction and/or body contouring are "intended" uses within the meaning of the regulations, and even assuming that the instructions are otherwise adequate for such procedures,[7] the Operator's Manual fails to list any indications for them. *See* Mot. at 17−18; Reply at 9. The "Intended Use and Indications for Use" section of the Operator's Manual reads as follows:

> The Vanquish is intended for use in applying therapeutic deep heat for selected medical conditions by applying electromagnetic energy in the radio frequency band of 27.12 megahertz and that is intended to generate deep heat within the body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

[6] Significantly, the *Weinstat* court's analysis was limited the federal statutes and regulations; that court had no occasion to consider the state statutes at issue in the present case.

[7] To the extent Zeltiq argues that the instructions do not adequately explain how to *operate* Vanquish for aesthetic procedures, there is insufficient (if any) evidence in the record to grant Zeltiq summary judgment on that basis, as previously discussed.

> Indications for use in applying therapeutic deep heat in body tissues for treatment of selected medical conditions such as: 1. Relieving pain; 2. Reducing muscle spasm; 3. Increasing range of motion of contracted joints using heat and stretch techniques; and 4. Increasing blood flow to tissues in the treatment area.

Hanrahan Decl. Ex. 3 at 5. Although the Operator's Manual apparently does not purport to provide a complete list of indications, none of the listed indications relate to the aesthetic uses for which Defendants marketed Vanquish.

The question of whether the Operator's Manual satisfies the adequacy standard set out in the FDCA regulations is only relevant, however, if those regulations also govern the standard for "adequate directions" under *California's* misbranding statute. Zeltiq cites only the general proposition that "[w]here the wording and objectives of a California statute are similar to the wording and objectives of a federal statute, California courts look to the interpretations of the federal statute for guidance in interpreting the state statute." Mot. at 17 (quoting *United States v. Johnson Controls, Inc.*, 457 F.3d 1009, 1021 (9th Cir. 2001)). That courts should generally interpret similar state and federal statutes similarly is not a controversial proposition. In this case, however, Zeltiq asks the Court to hold that the state law incorporates a complex and extensive regulatory scheme that, by its terms, applies only to the federal statute. Zeltiq cites no precedent for such an interpretation, and the Court is aware of no authority, either state or federal, applying the federal FDCA regulations to determine whether instructions are "adequate" for the purpose of California Health & Safety Code section 111375.

Asked to interpret a California statute, this Court "hesitate[s] prematurely to extend the law . . . in the absence of any indication from the [state] courts or the [state] legislature that such an extension would be desirable." *Del Webb Cmtys., Inc. v. Partington*, 652 F.3d 1145, 1154 (9th Cir. 2011) (quoting *Torres v. Goodyear Tire & Rubber Co.*, 867 F.2d 1234, 1238 (9th Cir. 1989)) (all but first alteration in original). The Court therefore declines to apply the federal regulations' formalistic requirements for "adequate directions" to the California statute. Zeltiq has not identified any evidence that the instructions for Vanquish are actually inadequate—e.g., that patients have been injured by physicians following that instructions, that operating Vanquish in the manner instructed creates any risk to patients, or that physicians find the instructions

insufficient to conduct any medical procedure with Vanquish, including the off-label aesthetic procedures at issue in this case. With no such evidence, the Court cannot conclude as a matter of law that Vanquish is misbranded under sections 111440 and 111375.

Accordingly, because Zeltiq has not shown that Defendants' branding of Vanquish was unlawful under any state law cited in its present Motion, the Motion is DENIED. The Court need not reach Defendants' preemption arguments.

IV. CONCLUSION

For the reasons stated above, Zeltiq has not presented evidence that Defendants violated California law, much less undisputed evidence of any such violation sufficient for Zeltiq to prevail on summary judgment. Zeltiq's Motion for Partial Summary Judgment on its UCL unlawful conduct claim is therefore DENIED.

IT IS SO ORDERED.

Dated: March 23, 2015

JOSEPH C. SPERO
Chief Magistrate Judge

United States District Court
Northern District of California